REMARKS

Objections to the claims:

Claims 1 and 3 have been amended as recommended by the examiner to obviate the objections.

Rejection of the claims under 35 U.S.C. § 112:

Claims 8, 10 and 12-14 have been rejected under 35 U.S.C. 112, fist paragraph, as containing new matter. Claim 8 has been amended to obviate the rejection. Specifically, claim 8 has been amended to recite a polyanion polymer having more that 80 monomer units. Support for the amendment can be found in the specification on page 7 lines 10 to 16. Also, in the examples: 34 kDa polylysine contains ~162 monomers, succinylated 34 kDa polylysine contains ~162 monomers, 49 kDa polyglutamic acid contains ~322 monomers, 36 kDa polyaspartic acid contains ~260 monomers, and pCILuc contains ~5,685 monomers, all of which are greater than 80 monomer units.

Rejection of the claims under 35 U.S.C. § 102:

Claims 1, 3, 4, 5, 7 and 19 have been rejected under 35 U.S.C. 102(e) as being anticipated by Lee *et al.* (U.S. Patent 5,907,777 and WO 97/00965). It is the applicants' opinion, that Lee did not teach the process taught by the applicants. Lee taught lipid encapsulation of a DNA/polycation complex. To facilitate the encapulsation, Lee taught that the DNA/polycation complex should be near neutral. However, to form small near neutral complexes (i.e. complexes that do not aggregate, column 5 line 58 to column 6 line 2) Lee uses either acid (column 6 lines 2-15), base (column 6 lines 16-21), or helper molecules (column 6, lines 22-46). The acid, base, or helper molecule is removed or neutralized prior to encapsulation with anionic lipids (column 6 lines 44-52). Applicants have amended the claims to further differentiate their method from the method of Lee *et al.* Specifically, claims 1 and 19 have been amended to recite the addition of a polyanion to form of a negatively charged complex. Support for the amendments can be found in the specification page 5 lines 7-10, page 18 lines 17-24, and page 19 lines 1-10. If the polyanion helper molecule, as taught by Lee, is not removed from the intermediate complex, and the intermediate complex is negatively charged, the negative charge of the complex would repel the negative charge of the anionic lipid used by Lee *et al.*, and encapsulation efficiency of the complex by the lipid would be reduced (Lee *et al.* column 2 lines 1-4).

Claims 8, 10, 12 and 14 have been rejected under 35 U.S.C. 102(e) as being anticipated by Wolff *et al.* (U.S. Patent 6,339,067 filed 12/30/1997). Applicants have submitted with this amendment, a §131 Declaration stating conception and testing of Applicants' processes prior to the filing date of the cited prior art.

Rejection of the claims under 35 U.S.C. § 103:

Claims 1, 3-5 and 7 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al (U.S. Patent 6,339,067 filed 12/30/1997). As stated in response to the 102 rejection, Applicants have submitted with this amendment, a §131 Declaration stating conception and testing of Applicants' processes prior to the filing date of the cited prior art.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 1, 3-8, 10, 12-14 and 19 should be allowable.

Respectfully submitted,

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I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as express mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date: 6/7/2004.

Kirk Ekena